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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|---------------------------------------|------------------|
| Offic Action Summary | Application No. | Applicant(s) |
| | 09/974,749 | YUAN, CHUN-SU |
| | Examiner Dr. Kailash C. Srivastava | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12/27/2002 as Paper Number 7.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22,30-38 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,15 and 16 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7, 10-14, 17-22, 30-38 and 51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Applicant's response and amendment filed 12/27/2002 as Paper Number 7 to election requirement in Office Action mailed 11/22/2002 as paper Number 6 is acknowledged and entered.
2. Claims 23-29 and 39-50 have been cancelled.
3. Claim 51 is added.
4. Claims 1-22, 30-38 and 51 are pending.

Restriction/Election

5. Applicant's election without traverse of Group I, Claims 1-22 and 30-38 filed 12/27/2002 as Paper Number 7 to election requirement in Office Action mailed 11/22/2002 as paper Number 6 is acknowledged and entered. Also acknowledged is applicant's election of species of alimentary as route of administration and of ginsenoside as composition in the response cited *supra* in complete response to the election requirement in Office Action mailed 11/22/2002 as paper Number 6. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 8-9, and 15-16 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Claims 1-7, 10-14, 17-22, 30-38 and 51 are examined on merits.

Objection to Information Disclosure Statement

7. The information disclosure statement filed 02/12/2002 as Paper Number 4 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed. Appropriate information should be provided.

Priority

8. Applicant's claim for domestic priority under 35 U.S.C. 119 (e) is acknowledged.

Consequently, Claims 1-22, 30-38 and 51 in the instant non-provisional application (U. S. Application Number 09/974749) are given the benefit of priority date of 11/07/2000.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 3, 10, 33, 35 and 38 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Phrases "antihyperglycemic constituent" in claims 3 and 35 renders those claims indefinite because it is not clear what does the word "constituent" refers? Another compound or component or composition. Examiner suggests that word constituent be replaced with word "compound".
- The phrase and "anti-obesity constituent" in claims 10, 33 and 38 renders those claims indefinite because it is not clear what does the word "constituent" refers? Another compound or component or composition. Examiner suggests that word constituent be replaced with word "compound".

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections – 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-7, 10, 17-19, 30-38 and 51 are rejected under 35 U.S.C. §102(b) as anticipated by JP 07267977A (English Abstract), with evidence provided by Gruenwald, J. et al (eds.), (PDR for Herbal Medicines. 1998. Medical Economics company, Montvale, N.J., Pg. 1009).

Claims recite a method to treat diabetes and obesity, said method comprising alimentarily administering an active compound from ginseng berry, wherein said compound

is ginsenoside Re and said ginseng is one of *Panax ginseng* or *Panax quinquefolius* (syn. *Panax quinquefolium*).

JP 07267977A (English Abstract) discloses administration as a health food of a compound (i.e., glycoside) obtained from *Panax ginseng* berries to treat diabetes (Title and abstract Lines 1 to 12). Please note that ginseng extract is comprised of a number of components (e.g., more than one ginsenoside including ginsenoside Re, water-soluble polysaccharides and polyenes) that constitute both ginsenosides and non-ginsenoside compounds (See Gruenwald, J. et al., PDR for Herbal Medicines. 1998. Medical Economics company, Montvale, N.J., Pg. 1009, Column 2, Lines 8-11). Please note that JP 07267977A (English Abstract) further discloses that the product obtained from ginseng berries may also be formulated into tablets and also the product to be a health food (Abstract Lines 7-8 and 14-15). Thus, the reference discloses a method to treat the same disease by administering the same material in the same form as a unit dosage (i.e., tablet) and via the same route (i.e., tablet is taken orally and is therefore, being administered alimentarily) to an individual in need thereof. Thus, the prior art product (i.e., extract from ginseng berries) is inherently comprised of same constituents and therefore, must inherently function as claimed (i.e., to treat diabetes and obesity) because the product disclosed in the prior art reference is comprised of the same compounds, is prepared and administered to an individual in the same way (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977) as is recited in the claimed invention.

Therefore, the reference is deemed to anticipate the cited claims.

Please note that Gruenwald, J. et al. is merely to support the chemical composition of ginseng extract and is not cited as a prior art reference.

Claim Rejections - 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-7, 10-14, 17-22, 30-38 and 51 are rejected under 35 U.S.C. § 103 (a) as obvious over JP 07267977A (English Abstract) in view of Yegorova et al. (U. S. Patent 6,399,089).

Claims recite a method to treat diabetes and obesity, said method comprising alimentarily administering an active compound/extract obtained from ginseng berry, wherein said compound is ginsenoside Re and said ginseng is one of *Panax ginseng* or *Panax quinquefolius* (syn. *Panax quinquefolium*).

Teachings from JP 07267977A (English Abstract) have already been discussed *supra*. JP 07267977A (English Abstract) intrinsically teaches a method of oral administration in form of a tablet of an extract obtained from *Panax ginseng* to treat obesity and diabetes.

JP 07267977A (English Abstract), however, does not disclose in detail the obesity treatment, the subject to whom treatment is given and the frequency of administering said composition.

Yegorova et al. discloses a method to treat both obesity and diabetes in a mammal, wherein the mammal is a human and the composition comprising panax ginseng extract is orally administered to said human two to three times daily (Column 3, Lines 28-30; Column 5, Lines 15-19; Column 9, Lines 49-56; Column 13, Lines 42-50; Column 14, Lines 1-2, 31-42, 60-61 and Column 15, Lines 10-12). Please note that Yegorova et al. further disclose that obesity is treated through weight loss and latter is accomplished through restricting caloric intake (Column 3, Lines 23-25) and discloses a method to restrict caloric intake and enhance insulin sensitivity via orally administering a composition comprising ginseng extract (Column 4, Lines 51-54).

One having ordinary skill in the art would have been motivated to modify teachings from JP 07267977A (English Abstract) according to the beneficial teachings from Yegorova et al., because both prior art references teach a method to treat obesity and diabetes or hyperglycemia by orally administering to an individual in need thereof a composition comprising an extract from ginseng, wherein said ginseng is *Panax ginseng* and the composition comprises an extract obtained from berries of said ginseng thereby providing to the individual in need thereof ginsenoside Re (JP 07267977A , English Abstract, Lines 1-14 and Yegorova et al., Column 3, Lines 23-30; Column 4, Lines 51-54; Column 5, Lines 15-19; Column 9, Lines 49-56; Column 13, Lines 42-50; Column 14, Lines 1-2, 31-42, 60-61 and Column 15, Lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from JP 07267977A (English Abstract) according to the beneficial teachings from Yegorova et al., because both prior art references teach a method to treat obesity and diabetes via orally administering a composition comprising *Panax ginseng* extract. While JP 07267977A (English Abstract) teaches a method to treat diabetes via orally administering an extract in tablet form obtained from *Panax ginseng* berries and intrinsically teaches that obesity is also treated by same method; Yegorova et al. remedies the deficiency in JP 07267977A (English Abstract) teachings, because Yegorova et al. beneficially teaches that obesity is treated through weight loss and latter is accomplished through restricting caloric intake (Column 3, Lines 23-25) and discloses a method to restrict caloric intake and enhance insulin sensitivity via orally administering a composition comprising ginseng extract (Column 4, Lines 51-54).

None of the prior art references cited above teach that the composition obtained from ginseng berries should be given pre-prandial. However, the adjustment of particular conventional working conditions (e.g., time, amounts and frequency for a particular treatment) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

29. No Claims are allowed.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JK
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Art Unit 1651
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April 3, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER